



# U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT  
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

H&I-3511  
(Redacted)  
D1076B

Telephone: [718] 965-5300

## WARNING LETTER

### CERTIFIED MAIL RETURN RECEIPT REQUESTED

January 8, 1997

Daniel Farrington  
President  
HomeoPet Llc.  
39 Locust Avenue  
East Moriches, NY 11940

Ref: 26-NYK-97

Dear Mr. Farrington:

This letter is in reference to the following veterinary homeopathic products which are distributed by your firm. These products make claims for their use in the treatment of various conditions. The product claims and indications are as follows:

#### **HOMEOPET MILIARY ECZEMA (FEMALE)**

Remedy to provide relief from Milary Eczema (Female).

Indications for use: Milary eczema, eosinophilic plaques, itching/violent itching, changes post spaying, hair loss due to spaying.

#### **HOMEOPET MILIARY ECZEMA (MALE)**

Remedy to provide relief from Milary Eczema (Male)

Indications for use: Milary eczema, eosinophilic plaques, itching/violent itching, changes post-castration, hair loss due to castration.

#### **HOMEOPET SKIN AND SEBORRHEA**

Remedy to provide relief from Skin Seborrhea Condition.

Indications for use: Seborrhea, hot dog syndrome, allergic dermatitis, itching, some eczemas, rough dry scaly skin, aggravated by heat or cold.

#### **HOMEOPET SINUSITIS**

Remedy to provide relief from Sinusitis.

Indications for use: Sneezing, feline upper respiratory infections, nasal discharges-light or heavy, obstruction of nasal passages due to foreign bodies, scabs on nose due to blockage or infection, dry nose, loss of taste, loss of smell.

### **HOMEOPET TRAUMA**

Remedy to provide relief from Trauma.

Indications for use: Bite wounds, cuts, bruising, sprains, teething, fever, bone fractures, bleeding into eye, assisting in reduction bleeding, extractions.

### **HOMEOPET URINARY INCONTINENCE**

Remedy to provide relief from Urinary Incontinence.

Indications for use: Old age incontinence, leakage during sleep, changes post-neutering, profuse clear watery flow in frequent but small amounts, incontinence associated with sleep, excitement or surgery.

### **HOMEOPET ANXIETY**

Remedy to provide relief from anxiety.

Indications for use: Separation from owner, separation from mother, left at kennel. Pet doesn't eat while owner is away, fretting, fear, hysteria (especially thunderstorms, fireworks, gunshots,) travel sickness, stress licking.

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### **HOMEOPET ARTHRITIS**

Remedy to provide relief from Arthritis.

Indications for use: Lameness, stiffness, pain on movement, difficulty rising after rest, rheumatic pains, inflammation of joints, cracking of joints, sore joints, back pain crossing over gait, destructive chewing, chronic sprain, bone deformity, degenerative reticula myelopathy, leg perthes, hip dysplasia.

### **HOMEOPET COUGH**

Remedy to provide relief from Cough.

Indications for use: Kennel cough, asthmatic cough, geriatric cough, croupy cough, wet heart cough, dry cough, deep cough, hysteria associated cough, difficulty swallowing, swollen glands.

### **HOMEOPET FLEAS**

Remedy to provide relief from Fleas.

Indications for use: Reaction to flea bites, allergic dermatitis (a) thick scabs (b) small blisters (c) prickly itching (d) smelly skin (e) eczema.

### **HOMEOPET HOT SPOTS**

Remedy to provide relief from Hot Spots.

Indications for use: All forms of eczema, wet eczema on skin, ears, paws between toes, inside joints, sore infected eczema, pruritic skin rash, hot smelly skin, vaginal eczema, scrotal eczema.

### **HOMEOPET GASTROENTERITIS**

Remedy to provide relief from Gastroenteritis.

Indications for use: Vomiting, food regurgitation, diarrhea, colic, flatulence, bloat due to retained gas, poor appetite, loss of appetite.

### **EquioPathics ASTHMA & ALLERGY**

Remedy to provide relief from Asthma & Allergy.

Indications for use: Coughing, sinusitis conditions, hysteria associated coughing, dyspnea (respiratory distress), asthmatic conditions (can help in emphysema), hay dust allergy, hay fever.

### **EquioPathics COAT**

Remedy to provide relief from Coat.

Indications for use: Eczema, itching (pruritus), dermatitis, nettle rash, seborrhea, ringworm, photosensitization, cracked skin, removal of toxins by improved urine function.

### **EquioPathics WORMS**

Remedy to provide relief from Worms.

Indications for use: Roundworm, tapeworm or hookworm infestation, debilitation (where animal's life is in immediate danger due to a massive worm infestation, veterinary advice should be immediately sought).

### **EquioPathics GASTROENTERIC-COLIC**

Remedy to provide relief from Gastroenteric-Colic.

Indications for use: Diarrhea, inappetence, colic (where shock is present, seek immediate veterinary care), flatulence, irritability, dysentery.

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### **EquioPathics HOOF**

Remedy to provide relief from Hoof.

Indications for use: Cracked hooves, poor hoof growth, dry hooves, sand cracks, weak white hooves and damage to hooves, eczema, laminitis, arthritis, warts and skin growths, vaccinosis, increases ability to absorb impacts.

### **EquioPathics MUSCULO-SKELETAL**

Remedy to provide relief from Musculo-Skeletal.

Indications for use: Muscular injury, lameness, sprains, tendon injuries, laminitis, navicular stiffness, pain on movement, arthritic conditions, laminitis (founder), bruised sole and bruising, spavins, splints, curb and windgall.

### **EquioPathics NOSE & SINUS**

Remedy to provide relief from Nose & Sinus.

Indications for use: Sinusitis, nasal discharge, sneezing, nasal blockage, inflammation of frontal sinuses.

### **EquioPathics URINARY DISFUNCTION**

Remedy to provide relief from Urinary Disfunction.

Indications for use: Fluid retention, urinary tract infection, jealousy, swelling and puffed up with fluid, suppressed urination due to anxiety and fear.

### **EquioPathics TRAVEL ANXIETY**

Remedy to provide relief from Travel Anxiety.

Indications for use: Fractionious animals, psychosomatic disorders, post-travel scour, hysterical response to being loaded or while being transported, trembling from fear, twitching and fidgety feet when boxed for travel, terrified reactions to entering darkness.

### **EquioPathics PRE-PERFORMANCE STRESS**

Remedy to provide relief from Pre-Performance Stress.

Indications for use: Fractious animals, psychosomatic disorders, teething scour, oversensitive young animals especially impatient, intolerant whining restlessness, colicky individuals, highly emotional animals, anxiety with palpitation.

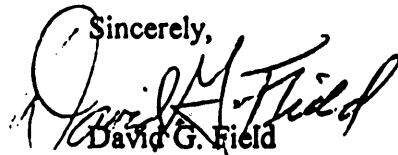
Use of these products by animal owners for the labeled claims could potentially endanger the health of the animal by delaying timely, appropriate treatment by a licensed veterinary practitioner.

All of the above listed products constitute both drugs as defined under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) and "new animal drugs" as defined under Section 201(w) of the Act in that they are not generally recognized as being safe and effective for use under the conditions prescribed, recommended or suggested in the labeling. As such these products are considered adulterated under Section 501(a)(5) of the Act.

The above is not intended to be an all inclusive review of all drug products marketed by your firm. It is your responsibility to ensure that all requirements of the Act and requirements of the implementing regulations promulgated thereunder are being met for all your products. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within the fifteen working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the Food and Drug Administration, 850 Third Avenue, Brooklyn, NY 11232, Attention: Fabio L. Mattiasich, Compliance Officer.

Sincerely,  
  
David G. Field  
Acting District Director

orig: addressee  
cc: HF1-35 (redacted)  
HFA-224  
HFC-210 (CFN 2436276)  
HFD-314  
HFR-NE1  
HFR-NE100  
HFR-NE140  
HFR-NE150 (GWQAP, Vitillo, Caparelli)  
EF (HomeoPet, LLC.)  
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